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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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COLLINS, CYNTHIA E	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,492	HEMERLY ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-128* is/are pending in the application.

4a) Of the above claim(s) *48 and 77* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-47,49-76 and 78-128* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *0604* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed July 20, 2004 has been entered.

Claims 1-28 are cancelled.

Claims 29-128 are newly added.

Claims 29-128 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Newly submitted claims 48 and 77 are directed to an invention that is independent or distinct from the invention originally elected for the following reasons: newly submitted claims 48 and 77 require the use of a vector comprising a nematode-induced promoter operably linked to the claimed DNA sequences, whereas the invention originally elected required only the use of a promoter functional in plants cells. A nematode-induced promoter is structurally distinct from a promoter that is generally functional in plants cells because a nematode-induced promoter contains structural motifs not found in promoters that are generally functional in plants cells. A nematode-induced promoter is functionally distinct from a promoter that is generally functional in plants cells because a nematode-induced promoter functions only upon nematode induction whereas a promoters that is generally functional in plants cells is presumed to function more or less constitutively. Accordingly the use of a vector comprising a nematode-induced promoter operably linked to the claimed DNA sequences would require an

additional search specifically directed to nematode-induced promoters and their use in plant cells.

Since applicant has received an action on the merits for the originally elected invention, prosecution on the merits is limited to this invention. Accordingly, claims 48 and 77 are withdrawn from consideration as being directed to a non-elected invention.

Claim Objections

Claims 30 and 59 are objected to because of the following informalities: claims 30 and 59 recite an acronym (TRP) that is not defined in the claims. Appropriate correction is required.

Claims 32-33 and 61-62 are objected to because of the following informalities: claims 32-33 and 61-62 recite an acronym (ACP) that is not defined in the claims. Appropriate correction is required.

Claims 41-45 and 70-74 are objected to because of the following informalities: the claims recite a nonelected sequence (SEQ ID NO: 9). Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to a DNA sequence encoding a protein that contains an intact TRP domain. The limitation "TRP" does not find support in the specification as originally filed, and thus constitutes new matter.

Claims 29, 31, 35-45, 49, 51, 53, 55, 58, 60, 64-74, 78, 80 and 82 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to a DNA sequence encoding a protein capable of modulating DNA replication in plant cells that comprises SEQ ID NO: 6 or an amino acid sequence having more than a % sequence identity to SEQ ID NO: 6 wherein the protein comprises a NH_2-terminal domain conserved in cdc27 homologues of different origin wherein the NH_2-terminal domain comprises a stretch of 161 NH_2-terminal amino acids and wherein the stretch comprises SEQ ID NO: 6 or an amino acid sequence having more than a % sequence identity to SEQ ID NO:6.

That an NH_2-terminal domain conserved in cdc27 homologues of different origin comprises a stretch of 161 NH_2-terminal amino acids and comprises SEQ ID NO: 6 does not find support in the specification as originally filed, and thus constitutes new matter.

That an NH_2-terminal domain conserved in cdc27 homologues of different origin comprises a stretch of 161 NH_2-terminal amino acids and comprises an amino acid sequence having more than a % sequence identity to SEQ ID NO: 6 also does not find support in the specification as originally filed, and thus constitutes new matter. The limitation "more than" in association with % sequence identity additionally does not find support in the specification as filed and thus constitutes new matter.

Claims 29-47, 49-76 and 78-128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth for claims 10-11, 14-15, 17-21 and 23-28 in the office action mailed April 13, 2004. This is a written description rejection.

Applicant's arguments filed July 20, 2004 have been fully considered but they are not persuasive.

Applicants assert that at least three examples of sequences which fall within the scope of claim 29 are described in the present specification. Applicants assert that those sequences are SEQ ID NO: 6 (which encodes cdc27A1 protein), SEQ ID NO: 14 (which encodes cdc27A2 protein), and SEQ ID NO: 15 (which encodes cdc27B protein). Applicants also point to the alignment presented in Figure 6 of the present application illustrating that the proteins encoded by those sequences comprise SEQ ID NO: 6 or a peptide having at least 50% amino acid identity with SEQ ID NO: 6. Applicants also

assert that the specification of the present application describes multiple species within the genus embraced by Claim 29. Applicants additionally assert that there is an implicit disclosure of more sequences because, based on the knowledge of explicitly described cdc27 sequences, one could isolate equivalent genes from other plant species using routine experimentation. Applicants further assert that it was known at the time the present application was filed that those equivalent genes may have some sequence variation, and that it would be recognized that isolation of such equivalent genes from other plant species is routine once the sequence of the *Arabidopsis* genes are known, i.e., based on the sequences described in the present application one can readily isolate the orthologue from another plant species. (reply page 18)

With respect to the sequences described in the specification, the Examiner first notes that that the sequences cited by Applicants (SEQ ID NOS: 14 and 15) were nonelected in the reply filed January 16, 2004 and withdrawn from consideration in the office action mailed April 13, 2004. Secondly the Examiner does agree that the specification describes three different sequences obtained from *Arabidopsis* that encode proteins designated cdc27A1, cdc27M and cdc27B, and that the specification describes the nonelected sequence of SEQ ID NO: 14 as encoding the cdc27A2 protein and the nonelected sequence of SEQ ID NO: 15 as encoding the cdc27B protein. The Examiner maintains, however, that the specification does not describe the elected sequence of SEQ ID NO: 6 as encoding the cdc27A1 protein; rather, the specification describes the elected sequence of SEQ ID NO: 6 as a 24 amino acid residue domain that is part of a conserved CDC27 N-terminal domain of the protein encoded by the nonelected sequence of SEQ ID NO: 9 (page 6 lines 3-29; sequence listing). The Examiner further maintains the

specification describes the nonelected sequence of SEQ ID NO: 9 as the sequence encoding the cdc27A1 protein (pages 36-37 Example 2).

With respect to Applicant's assertion that the specification of the present application describes multiple species within the genus embraced by Claim 29, the Examiner maintains that the disclosure of three different nonelected sequences obtained from a single species of organism is not a representative number of species sufficient to support the description of the broadly claimed genus which encompasses isolated DNA sequences obtained from any unspecified source that encode proteins that comprise the 24 amino acid residue domain of SEQ ID NO:6 or that comprise an amino acid sequence having more than 50% identity to the 24 amino acid residue domain of SEQ ID NO:6.

With respect to Applicant's assertion that there is an implicit disclosure of more sequences because, based on the knowledge of explicitly described cdc27 sequences, one could isolate equivalent genes from other plant species using routine experimentation, the Examiner maintains that one's ability to isolate equivalent genes from other plant species using routine experimentation does not describe the sequences of those equivalent genes. Whether a sequence is described is not dependent on whether the specification provides an enabling disclosure. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), which discusses the description of a claimed human cDNA sequence based on the disclosure of a rat cDNA sequence and a method for obtaining the human cDNA sequence:

> The patent describes a method of obtaining this cDNA by means of a constructive example, Example 6. This example, however, provides only a general method for obtaining the human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not

> provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5. The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. (*Lilly*, 43 USPQ2d at 1405)

With respect to Applicant's assertion that it was known at the time the present application was filed that those equivalent genes may have some sequence variation, and that it would be recognized that the isolation of such equivalent genes from other plant species is routine once the sequence of the *Arabidopsis* genes are known, such an assertion does not describe the sequences of those equivalent genes. See *University of California v. Eli Lilly* above.

Claims 29-47, 49-76 and 78-128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth for claims 10-11, 14-15, 17-21 and 23-28 in the office action mailed April 13, 2004.

Applicant's arguments filed July 20, 2004 have been fully considered but they are not persuasive.

Applicants submit that as described in the present specification the claimed nucleic acids are isolatable from genomic libraries by routine methods, and Applicants

submit that based on the sequences of the present invention it was possible to isolate a true cdc27 protein, without undue experimentation for the skilled person, because this isolation can be done by routing experiments like hybridization or PCR (reply page 19).

The Examiner maintains that the rejected claims are not directed to cdc27 protein coding sequences, as the rejected claims are directed to isolated DNA sequences that encode proteins that comprise the 24 amino acid residue domain of SEQ ID NO: 6 or that comprise an amino acid sequence having more than 50% identity to the 24 amino acid residue domain of SEQ ID NO: 6. The Examiner further maintains that it is unpredictable whether and what function such sequences would exhibit, as the 24 amino acid residue domain of SEQ ID NO: 6 represents only a small portion of a full length cdc27 protein.

Applicants also submit that in response to the Examiner's concern regarding the unpredictability of the effect of expressing a single peptide corresponding to only one exon (SEQ ID NO: 6) of a cdc27 protein that consists of sixteen different exons, newly submitted claim 29 now specifies that the protein comprises SEQ ID NO: 6 and is capable of modulating DNA replication in plant cells. Applicants further point to the specification in support of the newly added claims, which specification states at page 6 that the presence of exon SEQ ID NO: 6 is responsible for promoting Mc-substrate action and DNA-replication. Applicants further submit that the newly submitted claims are supported by the common knowledge that the N-terminus of cdc27 proteins harbors the highly conserved in CDCZ7/NUCZ-LIKE domain, and Applicants point out that SEQ ID NO: 6 corresponds to a large portion of this conserved domain. Applicants therefore submit that the effect of the presence of SEQ NO: 6 is a functional effect of the protein,

which functional effect is to the promote APC substrate action and therewith DNA-replication. Applicants additionally submit that with respect to undue experimentation the specification of the present application provides guidance to use proteins comprising SEQ ID NO: 6, and that no undue experimentation is necessary since the presence of SEQ ID NO: 6 is related to the biological function of the protein as it contributes to APC substrate activity and therewith in DNA replication. (reply pages 19-20)

The Examiner maintains that the rejection is not overcome by specifying that the protein comprises SEQ ID NO: 6 and is capable of modulating DNA replication in plant cells, because the specification does not provide sufficient guidance with respect to how to use the 24 amino acid residue domain of SEQ ID NO: 6 to promote APC substrate action and modulate DNA replication in plant cells. With respect to the functionality of SEQ ID NO: 6, the specification at page 6 in fact states that "the role of this domain is not currently known, but its conservation suggests that it is indispensable of CDC27 function" and that proteins comprising this novel exon sequence "may promote APC-substrate action and therewith allowing DNA-replication". The specification does not, however, disclose a specific function for SEQ ID NO: 6 or provide specific guidance with respect to how to use SEQ ID NO: 6 to achieve a specific function or a specific effect.

Applicants further submit that the Examples of the present application provide explicit teaching for making and using the claimed DNA sequence, and Applicants point in particular to Example 2 which describes the isolation of the cdc27A1 gene, which is an example of a sequence which comprises SEQ ID NO: 6 and is capable of modulating

DNA replication in plant cells, to Example 4 which describes mutant cdc27 proteins which comprise or lack SEQ ID NO: 6, to Example 5 which relates to cdc7 but is relevant for the description of the cloning steps and vectors, to Example 6 which is a prophetic example of how to obtain male sterility in plants using a mutant cdc27 protein, Example 7 which is a hypothetical example describing that the cdc27 muteins can be used to increase endoreduplication and which provides additional details on how to clone the mutants and transform them into plants, Example 8 which describes a study of the natural expression occurrence of the cdc27 protein which comprises SEQ ID NO: 6, Example 9 which describes cloning a gene encoding a cdc27A2 protein which comprises SEQ ID NO: 6, and Example 10 which describes the cloning of cdc27B protein, which comprises a peptide that is at least 50% identical to SEQ m NO: 6. (reply pages 20-21)

Further still Applicants point to experiments that they have conducted whose particular data does not appear in the specification. Applicants submit that tobacco plants transformed with cdc27A1 under the control of a 35S promoter showed improved characteristics such as improved growth characteristics, which is manifested by improved yield, improved plant height and improved biomass, as shown in Figure 2 attached hereto. Additionally, Applicants submit that these plants exhibited more cell division manifested by more branching, more leaves and bigger leaves as shown in Figures 2-4 attached hereto. Applicants also submit that *Arabidopsis* plants transformed with cdc27B under the control of a 35S promoter showed improved characteristics such as improved growth characteristics manifested by stay-green phenotype as shown in Figure 5 attached hereto. Figure 5 also shows that the transformed cells had more cell division as manifested by more branching and more leaves. (reply pages 21-22)

The Examiner maintains that the examples cited by Applicants are not commensurate in scope with the elected invention. The examples cited by Applicants are directed to the use of sequences nonelected in the reply filed January 16, 2004 (muteins, SEQ ID NOS: 5 and 9=CDC27A1, SEQ ID NOS: 11 and 14=CDC27A2, and SEQ ID NOS: 13 and 15=CDC27B) and withdrawn from consideration in the office action mailed April 13, 2004. While these examples are relevant to the extent that they support the functionality of the domain of SEQ ID NO: 6 in the context of a full-length CDC27 protein, the examples do not provide guidance with respect to how to make and use other sequences encoding proteins that comprise only SEQ ID NO: 6 or an amino acid sequence having more than 50% sequence identity to SEQ ID NO: 6 and that modulate DNA replication outside of this context.

With respect to the breadth of the claims, Applicants point out that the claims specify proteins which have to meet the following requirements: (1) Structurally, they must comprise SEQ ID N0: 6 or an amino acid sequence having more than 50% sequence identity to SEQ ID NO: 6, and (2) Functionally, they must be capable of modulating DNA replication in plant cells (reply page 22).

The Examiner maintains that in requiring that the isolated DNA sequence encode a protein whose structure is defined only by the single 24 amino acid residue domain of SEQ ID NO: 6 or some other amino acid sequence of unspecified length having only 50% sequence identity to SEQ ID NO: 6 and whose function is defined only as the capacity to modulate in an unspecified manner the replication of DNA in plant cells, the breadth of the claims is extreme.

With respect to the nature of the invention, Applicants assert that the present invention constitutes the first identification of a new class of proteins in plants and constitutes the first disclosure of methods to improve plant growth characteristics based on these proteins (reply page 22).

The Examiner maintains that the present invention constitutes the first identification in plants of an art-recognized class of eukaryotic cell-division control (cdc) proteins.

With respect to the level of one of ordinary skill, Applicants assert that at the time the present application was filed, the skilled person was aware how to determine whether a protein was capable of modulating DNA replication by checking the DNA level of the cells and/or the effect on cell division, for example, as described in the specification of the present application (reply page 22).

The Examiner does not dispute that the skilled person was aware how to determine whether a protein was capable of modulating DNA replication by checking the DNA level of the cells and/or the effect on cell division at the time of filing. The Examiner maintains, however, that at the time of filing the skilled person was not aware of which of the myriad sequences claimed would likely function to affect DNA replication or cell division (or other characteristics as claimed) in a specific manner and thus be a good candidate for plant transformation.

With respect to the amount of direction provided by the inventor, Applicants assert that a sufficient number of DNA species and structural features are given. Applicants also assert that sufficient guidance for making constructs and transgenic plants is given in the specification, as well as sufficient guidance with respect to the phenotype of such plants. (reply page 22)

The Examiner maintains that the specification, in disclosing only three different nonelected full-length coding sequences obtained from a single species of organism, does not provide sufficient direction with respect to discriminating between operative and inoperative embodiments of the myriad coding sequences comprising only the 24 amino acid residue domain of SEQ ID NO: 6 or an amino acid sequence having more than 50% identity to the 24 amino acid residue domain of SEQ ID NO: 6 that are to be used for transformation. With respect to the direction provided for making constructs and transgenic plants, the Examiner maintains that making constructs and transgenic plants was within the knowledge and abilities of one skilled in the art at the time of filing.

With respect to the existence of working examples, Applicants point out that the prophetic working examples set forth in the specification as filed are supplemented herewith by the experimental data discussed above (reply page 22).

The Examiner acknowledges above the examples referred to by Applicants

With respect to the quantity of experimentation needed to make or use the invention based on the content of the disclosure, Applicants submit that one would just

have to clone a cdc27 protein and transform it into a plant to see the effect on cell division and/or DNA replication (reply page 23).

That one would just have to clone a cdc27 protein coding sequence and transform it into a plant to see the effect on cell division and/or DNA replication does not necessarily imply that the quantity of experimentation needed to make or use the invention based on the content of the disclosure would be small. First, the claims are not directed to cdc27 protein coding sequences or limited to specific effects on cell division and/or DNA replication. Second, because the specification does not provide sufficient guidance for discriminating between operative and inoperative embodiments of the coding sequences to be used for transformation, one would have to test each and every cloned coding sequence for its effect on a plant cell or plant transformed therewith, and one would have no basis for assessing how many coding sequences one would need to clone and test in order to identify a single functional sequence meeting the structural limitations of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 is indefinite in the recitation of "promotes APC-substrate action". It is unclear what the protein does with respect to APC-substrate action, as the term "promote" is not a specific activity of a protein. It is also unclear what type of

action is promoted, as more than one type of action may occur between a substrate and other proteins, such as binding or catalytic action.

Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 is indefinite in the recitation of "allows DNA replication". It is unclear what the protein does with respect to DNA replication, as the term "allows" is not a specific activity of a protein.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 33 is indefinite in the recitation of "occupies the binding region of the APC complex". There is insufficient antecedent basis in the claim for the limitation " the binding region of the APC complex ".

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 33 is indefinite in the recitation of "inhibits the complex-substrate interactions". There is insufficient antecedent basis in the claim for the limitation "the complex-substrate interactions". It is also unclear what type of interactions are inhibited, as more than one type of interaction may occur between a substrate and other proteins, such as binding or catalytic action.

Claim 57, and claim 102 dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 57 is indefinite in the recitation of "the transplanted cells". There is insufficient antecedent basis in the claim for this limitation.

Claim 80, and claim 125 dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 80 is indefinite in the recitation of "modifying the characteristics". It is unclear what characteristics are modified, as plant cells and plants exhibit a plethora of different characteristics, whereas transformation of a plant cell or plant with a particular coding sequence would be expected to modify only a specific subset of these characteristics. It is also unclear in what way the characteristics are modified, as any given characteristic may be modified in different ways, whereas transformation of a plant cell or plant with a particular coding sequence would be expected to result in specific types modifications for specific characteristics.

Claim Rejections - 35 USC § 101

Claims 86 and 89-93 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Applicant's arguments filed July 20, 2004 in response to the rejection of cancelled claims 10-11 have been fully considered but they are not persuasive.

Applicants point out that the claims have been amended to recite an isolated DNA Sequence, as suggested by the Examiner (reply page 17).

Claims 86 and 89-93 are drawn to progeny and plant material, but are not limited to progeny and plant material that comprise the vector that was introduced into the parent plant. Due to Mendelian inheritance of genes, a single vector introduced into the parent plant would only be transferred to half of the progeny of that plant. Additionally, not all of the plant material of a transformed plant would necessarily comprise the vector that was transformed into the plant. Furthermore, given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny and plant material, it is unclear whether they would be distinguishable from progeny and plant material that would occur in nature. See *Diamond v. Chakrabarty,* 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo Inoculant Co.*, 233 U.S. 127 (1948), and *In re Bergey*, 195 USPQ 344, (CCPA). Accordingly, the rejection is extended to newly submitted claims 86 and 89-93. The amendment of the claims to indicate that the progeny and plant material comprise the vector that was transformed into the parent plant would overcome the rejection.

Claim Rejections - 35 USC § 102

Claims 86 and 89-93 are rejected under 35 U.S.C. 102(b) as being anticipated by Hemerly et al. (EMBO Journal, Vol. 14, No. 16, August 15, 1995, pages 3925-3936, Applicant's IDS).

Applicant's arguments filed July 20, 2004 in response to the rejection of cancelled claims 10-11 and 24-28 have been fully considered but they are not persuasive.

Applicants argue that the reference fails to describe the claimed DNA sequence, and point out that the claims have been amended to recite an isolated DNA Sequence, as previously suggested by the Examiner.

The rejection is extended to newly submitted claims 86 and 89-93, directed to progeny and plant material, as the claims do not sufficiently distinguish over progeny and plant material as they exist naturally, because the claims do not particularly point out any non-naturally occurring products. As discussed above in the rejection of the claims under 35 USC 101, the rejected claims do not require that the progeny and plant material comprise the claimed DNA sequence. Accordingly, the rejected claims are anticipated by any reference that discloses plants. The cited reference of Hemerly et al. anticipates the claimed invention because it discloses plants (page 3926, column 2, last paragraph). Amendment of the claims to indicate that the progeny and plant material comprise the vector that was transformed into the parent plant, as suggested above in the rejection of the claims under 35 USC 101, would overcome the rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins

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